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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,673	05/23/2005	Bianca Brogmann	Y2428-00163	1883
42109	7590	11/30/2007		
DUANE MORRIS LLP PATENT DEPARTMENT 1540 BROADWAY NEW YORK, NY 10036-4086				
EXAMINER				
HELM, CARALYNNE E				
ART UNIT		PAPER NUMBER		
4173				
MAIL DATE		DELIVERY MODE		
11/30/2007		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/510,673

**Applicant(s)**

BROGMANN ET AL.

**Examiner**

Caralynne Helm

**Art Unit**

4173

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/88)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-26 and 41-49, drawn to a pharmaceutical composition.

Group II, claims 27-32 and 50-51, drawn to method of making a pharmaceutical composition.

Group III, claims 33-40 and 52-54, drawn to method of treatment with a pharmaceutical composition.

The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: their common technical feature is not novel. The common technical feature of each group is a combination of ethylcellulose (or an ethylcellulose-based polymer) at least one fatty alcohol and at least two pharmaceutically active compounds, where the active compounds are released in a sustained, invariant and independent manner. Sackler et al. (EP0631781 A1) teach a pharmaceutical composition where the matrix provides independent, sustained and invariant release of the contained pharmaceuticals, where the combination of mu-opioid agonists and antagonists are included as contained pharmaceuticals (see page 3 lines 12-23). Further teachings by Sackler et al. state

Art Unit: 4173

that the matrix is comprised of ethylcellulose and an aliphatic alcohol (see page 8 lines 43-49). In addition, since a chemical and its properties are inseparable, the combination of the same components taught both by the applicant and Sackler et al. must also have the same properties (e.g. sustained, independent and invariant release). Thus since, a pharmaceutical composition where the matrix provides independent, sustained and invariant release of the contained pharmaceuticals is known in the art, this technical feature cannot be deemed as special.

### ***Election***

This application contains claims directed to the following patentably distinct species pharmaceutical compositions with at least two active compounds, their methods of production and their methods of use. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-54 are generic.

If Group I is elected then applicant is required to make an election for each of the following:

- The presence or absence of alkaline and/or water-swellaable substances (e.g. claim 4)
- The presence or absence of acrylic acid and/or hydroxyalkyl cellulose (e.g. claim 41)

Art Unit: 4173

- The presence or absence of particular classes of pharmaceutical excipients (e.g. claims 5-9, 42)
- The presence or absence of the opioid analgesic as a salt (see claims 12, 39, and 44)
- The presence or absence of the opioid antagonist as a salt (see claims 12, 39, 44, and 54)

If Group II is elected then applicant is required to make an election for each of the following:

- Whether the composition is made by granulation (e.g. claim 27)
- Whether the composition is made by extrusion (e.g. claims 28-32)

If Group III is elected then applicant is required to elect the specific pathology treated (e.g. opioid induced-obstipation or opioid induced-pruritus or idiopathic syndromes etc. – see claims 33-36 and 52)

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries) and the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention (and species, if applicable) to be examined even**

though the requirement may be traversed (37 CFR 1.143) and (ii) **identification of the claims encompassing the elected invention (and species, if applicable)**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of an invention (and species, if applicable) may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention (and species, if applicable).

Should applicant traverse on the ground that the inventions (and species, if applicable) are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions (or species, if applicable) to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions (or species, if applicable) unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention (or species, if applicable).

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Caralynne Helm whose telephone number is 571-270-3506. The examiner can normally be reached on Monday through Thursday 8-4 (EDT).

Art Unit: 4173

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel or Cecilia Tsang can be reached on 571-272-0718 or 571-272-0563, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Caralynne Helm  
Examiner  
Art Unit 4173

CH

/Cecilia Tsang/  
Supervisory Patent Examiner, Art Unit 4173